



SPL Pathways

Pathways for successful creation & submission of SPL R4 Documents
Scenarios eBooks Series

Selecting an SPL Authoring Tool or Solution

Version 1.0

Purpose: This SPL R4 training Pathways eBook is to be utilized as an information resource by companies who need to submit SPL documents to FDA for the registration of drug establishments and/or listing of drug products to determine a suitable SPL authoring tool or solution.

Note: FDA does not endorse any SPL authoring software or SPL conversion vendors

Similar to the electronic submission of electronic tax documentation to the United States Internal Revenue Service, there are various options for the preparation of electronic drug establishment registration and drug listing data in SPL format.

1. Utilize SPL authoring software with features which assist with the entry and validation of data: Various SPL authoring software
2. Provide data to SPL conversion service which create the SPL files and submit the files for you.
3. Create SPL document using free fillable forms: SPL Xforms

SPL software or conversion vendors - <http://spl-work-group.wikispaces.com/Vendors>

SPL Xforms - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm>

Whichever option you choose should result in the creation of valid SPL documents.



SPL Conversion Vendor

SPL Xforms

SPL Authoring Software